

RFE MEMO

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Product Description(s): Human TIMP-1 Kit **Catalog Number(s) / Size(s):** K151JFC-Series **Lot Number:** K0040370

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0040370 has been extended to 30 Apr 2019.

The expiration dates for the following kit components have also been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
Human TIMP-1 Plate	Z0055700	28 FEB 2019	30 APR 2019
Anti-hu TIMP-1 Antibody	D0040632	31 DEC 2018	30 APR 2019
Human TIMP-1 Calibrator	A0040181	28 FEB 2019	30 APR 2019
Diluent 2	M0020090	30 APR 2018	30 APR 2019
Diluent 3	M0030071	30 SEP 2018	30 APR 2019

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	Dawn Stollar	16 APR 2018

This memo supersedes all other statements regarding date of expiration for this product.

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Product Description:	Human TIMP-1 Kit
Kit Catalog Numbers:	K151JFC-1, K151JFC-2, K151JFC-4
Kit Lot Number:	K0040370
Expiration Date:	30 Apr 2018

Acceptance Data/ Percent Recovery Specifications:

		Calibrator Control 1			Control 2		Control 3		
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	Human TIMP-1	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

		LLOQ				ULOQ	
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	Human TIMP-1	494	80% - 120%	< 20%	32000	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
	10X Calibrator	365000	pg/mL	
	Human TIMD 1	Control 1	715000	pg/mL
1	1 Human TIMP-1	Control 2	211500	pg/mL
		Control 3	70500	pg/mL

Concentrations provided in this table refer to the stock concentration of the calibrators. For top of the standard curve concentrations, please refer to the Standard Curve Data

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Standard Curve Data:

Human TIMP-1 - Spot 1				
Conc. pg/mL	ECL Signal	%CV		
36500	1,320,000	1.7		
12200	398,000	3.9		
4060	82,600	4.2		
1350	13,200	4.5		
451	2,390	5.5		
150	571	3.5		
50.1	212	3.6		
0.00	81	4.0		

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human TIMP-1 Plate	Z0055700	2-8°C	28 Feb 2019
Anti-hu TIMP-1 Antibody	D0040632	2-8°C	31 Dec 2018
Human TIMP-1 Calibrator	A0040181	\leq -70°C	28 Feb 2019
Diluent 2	M0020090	\leq -10°C	30 Apr 2018
Diluent 3	M0030071	\leq -10°C	30 Sep 2018
Read Buffer T (4X)	Not Kit Specific	Room temperature	N/A

Statement:

The above kit was tested using MSD procedures and it conforms to MSD's specifications. The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Vanessa Castleberry	Quality Assurance	Vanessa Castlebing	27 SEP 2016